REMARKS

Applicants have amended claims 11, 23, and 25 to replace the phrase "alpha hemoglobin stabilizing protein (AHSP) knock out mouse" with a reference to the transgenic mouse of claim 1. No new matter has been introduced into this application by reason of any of the amendments presented herewith. Entry of the foregoing amendment is respectfully requested.

TRAVERSAL OF RESTRICTION REQUIREMENT

A restriction requirement under 35 U.S.C. §121 was set forth in the Official Action dated January 26, 2005 in the above-identified patent application. It is the Examiner's position that claims 1-38 in the present application are drawn to eighteen (18) patentably distinct inventions which are as follows:

Group I: Claims 1-4 drawn to a mouse harboring homozygous null mutation in the alpha hemoglobin stability protein (AHSP) gene;

Group II: Claims 5-8 drawn to a mouse harboring heterozygous null mutation in the AHSP gene;

Group III: Claims 9-13 drawn to a method of screening for therapeutic agents which effect AHSP using the mice of claim 1;

Group IV: Claims 14-16 drawn to a method of diagnosing an AHSP-related disorder in a test subject;

Group V: Claim 17 drawn to a method of screening for compounds which modulate the activity of an AHSP polypeptide, wherein the method comprises contacting at least one test compound with the AHSP polypeptide in a reaction medium;

Group VI: Claim 18 drawn to compounds identified by the screening methods of claim 11 or 17;

Group VII: Claims 19-22 drawn to a method of treating ameliorating symptoms of an AHSP-related disorder by overexpressing an AHSP encoding nucleic acid molecule in a patient;

Group VIII: Claims 23-26 drawn to a method of producing anti-AHSP antibodies and anti-AHSP antibody preparations;

Group IX: Claim 27 drawn to a kit comprising one or molecules for the detection of AHSP expression;

Group X: Claim 28 drawn to transgenic mice which overexpress AHSP;

Group XI: Claim 29 drawn to a mouse having a homozygous null mutation in the AHSP gene and a heterozygous null mutation in beta major and minor globulin genes;

Group XII: Claims 30 and 31 drawn to methods for assessing the activity of compounds useful for the treatment and/or prevention of an AHSP-related disorder;

Group XIII: Claim 32 drawn to a compound identified by method of claim 30;

Group XIV: Claim 33 drawn to a method of treating or ameliorating symptoms of an AHSP-related disorder by administering the compound of claim 32;

Group XV: Claim 34 drawn to a mouse having a homozygous null mutation in the AHSP gene and a homoozygous null mutation in at least one alpha globulin gene;

Group XVI: Claims 35 and 36 drawn to a method of assessing the activity of compounds useful in the treatment and/or prevention of an AHSP-related disorder using the mice in claim 34;

Group XVII: Claim 37 drawn to a compound identified by the method of claim 35; and

Group XVIII: Claim 38 drawn to a method of treating or ameliorating symptoms of an AHSP-related disorder comprising administering the compound of claim 37 to a patient.

The Examiner has further indicated that Groups III and VI; Groups V and VI; Groups I and III; Groups XI and XII; Groups XV and XVI; Groups I and VII; Groups XI and XIV; Groups XV and XVIII; Groups XII and XIII; Groups XVI and XVII; Groups VI and VII; Groups XIII and XIV; and Groups XVII and XVIII are related as product and process of use as described in MPEP

§806.05(h).

Applicants note that the MPEP at §821.04 states:

> "Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP §806.05(f) and §806.05(h)... However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined."

The Examiner has determined, at page 6 of the instant Official Action, that Group I is related to Group III (i.e., claims 9-13) as product and process of use. Applicants have amended claim 11 of Group III to recite that the AHSP knock out mouse employed in the method is the transgenic mouse of claim 1. Accordingly, the claims of Group III specifically recite all of the limitations of claim 1 of Group I.

Additionally, the Examiner has noted that Groups I and VII (i.e., claims 19-22) are related as product and process of use (at page 7 of the instant Official Action). However, Applicants note that the Group VII invention, along with the Group XIV and XVIII inventions, are currently not limited to methods of treating mice, as indicated by the Examiner. Indeed, claims 19-22, 33, and 38 of Groups VII, XIV, and XVIII, respectively, clearly recite administering a compound to a patient having an AHSP related disorder. Clearly, a patient is not limited to a mouse. Nonetheless, Applicants anticipate rejoinder of Groups III and VII upon the allowance of a product claim of Group I and the satisfaction of the other requirements set forth in §821.04 of the MPEP.

Applicants also note that the Examiner has not set forth how Group VIII (i.e., claims 23-26) is related or unrelated to the other Groups. It is the Applicants position that Group VIII is clearly related to Group I as product and process of

use as described in MPEP §806.05(h). Indeed, claims 23-26 are drawn to methods of producing AHSP specific antibodies in mice which harbor a homozygous null mutation in the AHSP gene. Additionally, claims 23-26 have been amended to specifically depend from claim 1 of Group I. Inasmuch as the claims of Groups VIII recite all of the limitations of claim 1 of Group I, Applicants respectfully request the claims of Group VIII be rejoined and examined on their merits upon the finding that claim 1 is allowable.

Applicants also respectfully traverse the restriction between Group I and Groups II, XI, and XV. A withdrawal of the restriction requirement is clearly in order for the reasons set forth below.

According to the MPEP at §803, two criteria must be satisfied in order to warrant restriction:

1) the inventions must be independent and distinct as claimed; **and**
2) there must be a **serious burden** on the Examiner if the restriction is not required. [Emphasis added.]

Indeed, "if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions" (MPEP at §803). Notwithstanding the Examiner's assertion to the contrary, it is apparent from an objective reading of Groups I, II, XI, and XV that they are drawn to closely related subject matter and the examination of Groups I, II, XI, and XV together cannot be reasonably regarded as imposing a "serious burden" on the Examiner.

Group I is drawn to, as noted by the Examiner, a mouse harboring a homozygous null mutation in the alpha hemoglobin stabilizing protein (AHSP) gene. Notably, Group II is drawn to a mouse harboring a heterozygous mutation in the AHSP gene. Applicants submit that a search for a mouse having null mutations in both alleles of the AHSP gene (i.e., Group I)

would encompass a search for a mouse having a null mutation in one of the alleles of the AHSP gene (i.e., Group II). Accordingly, Applicants respectfully submit that searching both the Group I and II inventions cannot be reasonably regarded as imposing a "serious burden" on the Examiner, as required by the MPEP at §803 for a proper restriction requirement. Notably, the class and subclass classifications of both the Group I and Group II inventions are the same.

Similarly, Applicants submit that a search of Group I would necessarily involve a search of Groups XI and XV. Claims 29 and 34 of Groups XI and XV, respectively, depend from claim 1 of Group I. Accordingly, the mice of Groups XI and XV, as noted by the Examiner, are mice harboring a homozygous null mutation in the AHSP gene. The mice of Groups XI and XV additionally harbor a heterozygous null mutation in the beta major and minor globulin genes and a homozygous null mutation in at least one alpha globulin gene, respectively. Applicants respectfully submit that a search of Group I **necessarily** encompasses the searches of Groups XI and XV and, therefore, it cannot be reasonably held that the search of Groups XI and XV would present a "serious burden" for the Examiner. Indeed, a transgenic mouse that satisfies the features of claim 29 (i.e., Group XI) or claim 34 (i.e., Group XV) necessarily satisfies claim 1 of Group I. It is also noteworthy that the class and subclass classifications of Groups I, XI, and XV are identical.

Upon the removal of the restriction between Groups I and Groups XI and XV, Applicants submit that the claims determined to be related to Groups XI and XV as product and process of use should be rejoined upon the satisfaction of the requirements set forth in §821.04 of the MPEP. Specifically, the Examiner has indicated that Groups XII and XIV are related as product and process of use to Group XI and that Groups XVI and XVIII are related as product and process of use to Group

XV (see pages 6-7 of the instant Official Action).

Finally, while the United States Patent and Trademark Office has a legitimate interest in obtaining proper revenue from filing and issuance fees, it does not have the unrestrained power to tax inventors. The Applicants are entitled to obtain patent protection on each novel aspect of the invention, namely transgenic mice harboring at least one null mutation in its AHSP gene, optionally with mutations to the beta major and minor globulin genes or at least one alpha globulin gene, and methods of use thereof. If Applicants are forced to divide this application into ***eighteen*** (18) separate patent applications as a result of the restriction requirement imposed by the Examiner, the Applicants will be unduly and unfairly burdened with excessive fees and cost associated with the prosecution and maintenance of eighteen patents, as contrasted to a single or, at the very least, a few patents.

However, in order to be fully responsive to the instant restriction requirement, Applicants hereby elect, with traverse, the subject matter of Group I, i.e. claims 1-4, for examination.

Applicants' elections in response to the present restriction and election of species requirements are without prejudice to their right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation

By 

Robert C. Netter, Jr., Ph.D.
PTO Registration No. 56,422

Telephone: (215) 563-4100
Facsimile: (215) 563-4044